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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/502,283	02/11/2000	Sun Ai Raillard	02-029510US	4948

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EXAMINER

PRASTHOFER, THOMAS W

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 12/04/2001

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*file copy*

Application No.

09/502,283

Applicant(s)

RAILLARD ET AL.

Examiner

Thomas W Prasthofer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 27-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 18-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

Detailed Action

Status of the Application

Receipt is acknowledged of a response to a restriction requirement on 10 September 2001 (Paper No. 11).

Status of the Claims

Claims 1-71 are pending in the present application. Claims 27-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Claims 1-26 are being examined on their merits.

Response to Restriction and Election of Species with Traverse

Applicant's election with traverse of claims 1-26 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the search of Groups I and II would be coextensive and it would therefore not be a burden to search both inventions. This is not found persuasive because, as stated in the restriction requirement mailed 02 July 2001, the inventions of Groups I and II involve different method steps and would therefore require different searches involving different search terms and the searches would not be coextensive.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The references cited in the information disclosure statement received 09 August 2000 (Paper No. 7) are not with the application and are not available to the examiner. The examiner requests that applicants provide copies of the references so that they may be considered.

Objections to the Claims

1. Claims 18-26 are objected to because they depend from rejected claims.

Claims Rejections – 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, the metes and bounds of “*an off-line parallel adjustment of cell growing conditions*” is not clear. The specification provides examples of such adjustments but one of ordinary skill in the art would not be able to determine what types of “*adjustments*” are to be included or excluded. For example, would lysis of cells be considered an “*adjustment?*” Would removing a cell from one plate by trypsinisation and placing it into a new plate be considered an “*adjustment?*” It is also not clear what distinguishes “*parallel*” adjustments from non-parallel adjustments. Clarification is requested.

B. In claim 1, it is not clear if column separation is to be excluded entirely from the method or if it is not excluded between steps (ii) and (iii).

C. In claim 1, method step (iii), it is not clear what the metes and bounds of “*performing flow-injection analysis using electrospray tandem mass spectrometry*.” The claim recites that one obtains mass-to-charge data but it is not clear what type of analysis is being performed (e.g. detecting binding, decomposition, specific activity, cell death, etc.).

D. In claim 1, it is not clear what the metes and bounds of “*component*” are. For example, are water from the cytosol, a mitochondrion, a membrane, a nucleus, and sodium ions all included in the term “*component?*” Clarification is respectfully requested.

E. In claim 2, it appears that performing method steps (i) and (ii) simultaneously requires that the cells be alive and growing during, excluding cell lysis and organic solvent extraction, for

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example, from the method. If this is the case, applicant is requested to make this clear in the claim. If this is not the case, additional method steps may be required between method steps (ii) and (iii). Clarification is respectfully requested.

F. Claims 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: method steps related to a functional assay for determining the activity of a component or a means of relating a detected product with an activity.

G. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 5 recites the broad recitation "*at least about 500 cell colonies*," and the claim also recites "*at least about 1000 (and higher) cell colonies*" which is the narrower statement of the range/limitation. Also, claim 6 recites the broad recitation "*at least about 200 cell colonies*," and the claim also recites "*at least about 1000 (and higher) cell colonies*" which is the narrower statement of the range/limitation.

Claims Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1 and 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Chace U.S. Patent 6,258,605 B1.

The Chace reference discloses a method of using tandem mass spectrometry for genetic screening of newborns (abstract). Whole blood (comprising one or more cells grown in the newborn) is collected and placed onto filter paper (an off-line adjustment of cell growing conditions and solid support) and methanol is used to extract (purify) components from the cells (column 2, line 50 – column 3, line 11). The methanol (volatile and buffered with amino acids) is removed through evaporation. The final residues are placed into an autosampler tray for application to the MS. Obtaining charge-to-mass ratios is disclosed in column 7, lines 29-34. Consequently, present claims 1, 12, 13, and 17. The amino acids and other metabolic analytes (e.g. carnitine, palmitoylcarnitine, ornithine, and alanine) are known in the art to be both the products of enzymatic reactions and substrates for enzymatic reactions, palmitoylcarnitine, for example, possessing a hydrophobic moiety, anticipating present claims 14-16.

Allowable Subject Matter

4. Claims 18-26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas Prasthofer** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

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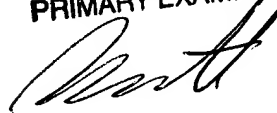
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Thomas Prasthofer, Ph.D.

December 2, 2001



BENNETT CELSA
PRIMARY EXAMINER



12/3/01